Appl. No. 10/078,927

Filed: February 19, 2002

Page 5

Remarks

Claims 1-15, 23, 25 and 32 are pending. All claims have been rejected. In the present response claims 1, 2, 4-6, 8 and 32 have been amended and claims 3, 9, 12, 23 and 25 have been canceled without prejudice. New claim 33 has been added. Support for the amended claims is found throughout the specification as described in the remarks of Applicants Amendment and Response to Final Office Action date April 25, 2005. Support for new Claim 33 is found throughout the specification and claim 1, as originally filed. No new matter has been added by way of this amendment. Reconsideration and withdrawal of the rejections are respectfully requested in light of these amendment and the following remarks.

In the Advisory Action issued on May 18, 2005, the Examiner did not enter the amendment for the following reasons: (1) the amendment raises new issues that would require further consideration, (2) the amendment raises the issue of new matter, (3) the amendment is not in compliance with 37 CFR 1.121, and (4) the sequence listing filed does not comply with the sequence rules.

In response to the Examiner's assertion that the amendment raises new issues that would require further consideration, Applicants submit herewith a request for continued examination and the associated fees.

In response to the previous amendment's noncompliance with 37 CFR 1.121, Applications herein submit a corrected set of claims that contain the proper status identifier for claims 1, 2, 4-6, 8, 32 and 33.

In response to the Notice to Comply with Requirement for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, Applicants herein submit a replacement disc containing the sequence and a statement that the content on the computer readable copy is the same as the paper copies included with Applicants amendment filed on April 25, 2005.

In response to the Examiner's assertion that the amendment raises the issue of new matter because the Examiner can find no statement in the specification that this Accession Number is properly incorporated by reference, Applicants respectfully disagree. Mouse Dab1 is defined on page 4, lines 22-25 as a protein having the sequence

Appl. No. 10/078,927 Filed: February 19, 2002

Page 6

found in genbank no. 1771281 and is more than a "mere reference to another application, patent, or publication...".

The proteins, Dab1 and Cdk5, included in the claimed methods are well known in the art and references to scientific literature and/or genbank accession numbers disclosing the structure (amino acid sequence) of these proteins have been provided in the specification. Applicants continue to argue, as in previous office action responses, that because the structures of these proteins are well known in the prior art, these structures do not need to be reproduced in the specification and in fact are preferably omitted according to Hybridtech, Inc. v. Monoclonal Antibodies, Inc. 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986) ("a patent need not teach, and preferably omits, what is well known in the art")(citing Lindemann Machinenfabrik v. American Hoist & Derrick, 730 F.2d 1452, 1463, 221 U.S.P.Q. 481, 489 (Fed. Cir.1984)); see also Webster Loom Co. v. Higgins, 105 U.S. 580, 585-586 (1882). Applicants maintain that Cdk5 and Dab1 proteins were familiar and well understood by those of skill in the art at the time the present application was filed and could easily be distinguished from other related proteins. These terms are in fact creations of the art used to denote, in each case, a class of proteins with features that allow them to be grouped together and distinguished from other proteins. Based on the prior art, a skilled artisan would be able to routinely identify any Cdk5 protein that has the Cdk5 serine kinase activity of the present invention and a Dab1 protein within a biological sample with the structural properties of the claimed invention, i.e., a serine at the 491 or 515 positions.

However, in an attempt to further prosecution, in Applicant's response dated December 13, 2004 to the office action rejection dated September 16, 2004, Applicants revised Claim 32 to recite a GenBank accession number. The was done in light of the Examiner's statements in the office action dated September 16, 2004 pages 13 [14] and the first paragraph of page 15. On page 13 the Examiner states: "while being enabling for a method for detecting the presence of Cdk5 kinase activity by immunoprecipitating human Dab1 having GenBank accession number 3288851 or mouse Dab1 having GenBank accession number 1771281 from a biological sample with or without Cdk5; ...".

On page 15, the Examiner asserts "the disclosure is limited to a method for detecting the

Appl. No. 10/078,927 Filed: February 19, 2002

Page 7

presence of Cdk5 kinase activity by immunoprecipitating human Dab1 having GenBank accession number 3288851 or mouse Dab1 having GenBank accession number 1771281 from a biological sample with or without Cdk5;...".

As shown on page 8 [d] of the final office action mailed January 26, 2005, the Examiner was capable of finding the Dab1 protein sequence in genbank. Therefore, one of skill in the art could easily find the murine Dab1 sequence based on the definition of murine Dab1 found in the specification.

The Examiner also asserts that accession number 1771281 has been modified no less than 4 times and lists the sequence of a polypeptide referred to as "mDab555" not Dab1. Therefore, it is the Examiner's opinion that the scope of polypeptides that are encompassed by the term "GenBank accession number 1771281" is unclear. Applicants argue that in none of the modifications made to GenBank accession number 1771281 was the amino acid sequence of the protein changed. Furthermore, Dab1 is the official symbol for the nucleic acid sequence encoding this protein. Therefore the term "GenBank accession number 1771281" provides a clear description of the murine Dab1 protein.

Applicants further note that the U.S. Patent Office has previously accepted the use of genbank accession numbers in claims to refer to biological sequence information known and available in the prior art. For example, U.S. Patent No. #6,770,742, issued August 3, 2004 claims a fibroblast growth factor receptor-4 by reference to a GenBank accession number. The FGFR-4 sequence is not listed in the sequence listing, thus there is no SEQ ID qualifier for the FGFR-4 receptor. Furthermore, the revision history for this GenBank accession number shows that it was revised no less than 7 times. Since there appears to be no per se rule against the use of genbank accession numbers in claims, Applicants would ask the Examiner to reconsider and allow their use in this instance where the sequence itself does not go to the heart of the invention, but is simply useful information for understanding the invention.

In the final office action dated January 26, 2005, the Examiner stated on page 4, 1ST paragraph, "It is suggested that applicants clarify the scope of polypeptides that are considered to be a "Cdk5" or "Dab1" polypeptide by, for example, identifying their intended Cdk5 or Dab1 polypeptide by a sequence identifier." and on page 8, the last

Appl. No. 10/078,927

Filed: February 19, 2002

Page 8

sentence of paragraph [d] "that applicants identify the sequence of mouse Dab1 having GenBank accession number 1771281 by a sequence identifier".

Therefore, again in an attempt to further prosecution, the Applications included a sequence identifier into the claims based upon the definition given to Dab1 which states that the mouse Dab1 protein sequence is found in genbank accession number 1771281.

In the Advisory Action date May 18, 2005, the Examiner is now asserting that the inclusion of SEQ ID NO:4 is new matter because there is no statement in the specification that this Accession Number is properly incorporated by reference.

Under definitions, on page 4, line 25 of the specification, Applicants specifically defined mouse Dab1 protein as having the amino acid sequence listed in genbank accession number 1771281. Applicants assert that this definition is more than a mere reference to another application, patent, or publication.

Applicants request that the Examiner reconsider the assertion that (1) Cdk5 and Dab1 are not well known in the art, (2) inclusion of an accession number renders the claims unclear and (3) inclusion of SEQ ID NO:4 is new matter.

It is not believed that extensions of time or fees are required. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 501968.

Respectfully submitted,

Shawn a. Hawlais

Shawn A. Hawkins Registration No. 50,318

St. Jude Children's Research Hospital 332 N. Lauderdale Memphis, TN 38105

Phone: 901-495-2751